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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/192,579	11/17/1998	FRANCO MENOZZI	960-34	9973
7590 07/19/2004 NIXON AND VANDEHYDE 1100 NORTH GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/192,579

Applicant(s)

MENOZZI ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12May2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56-70 and 82-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-67 is/are rejected.
- 7) ☒ Claim(s) 68-70, 82-84 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

#### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14April2004, has been entered.
2. Claims 66 has been amended. New Claims 82, 83, and 84 have been entered.
3. Claims 56-70 and 82-84 are pending and under consideration.

#### **Rejections/Objections Maintained**

4. The rejection of claims 56-67 under 35 U.S.C. 102(b) as being anticipated by Menozzi et al (*Abstracts of the General Meeting of the ASM*, 95(0):193, abstract B-159) is maintained for reasons of record.

Applicants argue that Menozzi et al do not disclose any structural characterization of the protein HBHA, but only functional characteristics. In addition, Menozzi et al do not disclose any probes or procedures for cloning the gene coding for HBHA nor what microorganisms to express it. The Declaration of Dr. Franco Danie Menozzi also argues that the reference is not enabling for the production of HBHA.

The examiner has considered applicants argument and the Declaration of Dr. Menozzi, but does not find them persuasive for the reasons put forth in the Office Actions of record to date. The instant claims are drawn to a product, HBHA, and not to a method of making. In past Office Actions, the examiner has stated that in the absence of evidence to the contrary, the product taught by Menozzi et al and the product of the instant claims are one and the

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same. This is based upon the evidence that: 1) the instant inventors and their laboratories are also authors on the cited reference, 2) both products have the identical name, 3) both products are from identical mycobacterial sources, and 4) both products have identical characteristics.

Due to the evidence that the product of Menozzi et al and the instant claims are identical, the amino acid sequence and monoclonal antibody binding characteristics are inherent properties of HBHA.

To date, neither the inventors nor the Declaration have put forth evidence that the HBHA product of the instant claims is not the HBHA product of Menozzi et al. Instead, the inventors and the Declaration merely argue that Menozzi et al is not enabled. However, Menozzi et al do teach: 1) bacterial source, 2) cell wall origin, 3) molecular weight, 4) specific erythrocyte agglutination activities, 5) mycobacterial auto-agglutination activity, 6) specific sulfated polysaccharide inhibition characteristics, and 7) specific lack of inhibition of agglutination activity by non-sulfated sugars. This knowledge is sufficient to enable one of ordinary skill in the art to produce the claimed product.

5. The objection to claims 68-70 as being dependent from rejected claims is maintained for reasons of record.

### **Claim Objections**

6. Newly added claims 82-84 are objected to as being dependent from rejected claim 60.

### **Conclusion**

7. Claims 56-67 are rejected. Claims 68-70 and 82-84 are objected to as being dependent from rejected claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)


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272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

July 14, 2004